

WHAT IS CLAIMED IS:

1. A pharmaceutical composition made by a method comprising
atomizing a liquid formulation of a therapeutic or prophylactic agent to produce an
atomized formulation,
freezing said atomized formulation to form solid particles, and
drying said solid particles at about atmospheric pressure to produce dried particles,
wherein said drying is performed in the presence of vibration, internals, mechanical stirring, or a
combination thereof.
2. The pharmaceutical composition of claim 1, wherein said frozen, solid particles are in a
fluidized state as they are being dried.
3. The pharmaceutical composition of claim 1, wherein said dried particles have a volume
mean diameter of between about 35 μ m and about 300 μ m.
4. The pharmaceutical composition of claim 1, wherein said dried particles have a volume
mean diameter of between about 50 μ m and about 100 μ m.
5. The pharmaceutical composition of claim 3, wherein at least about 50% of said dried
particles have a volume diameter within about 80% of the mean.
6. The pharmaceutical composition of claim 1, wherein said dried particles have a mean
aerodynamic diameter of between about 8 μ m and about 140 μ m.
7. The pharmaceutical composition of claim 1, wherein said dried particles have a mean
aerodynamic diameter of between about 20 μ m and about 70 μ m.

8. The pharmaceutical composition of claim 1, wherein said freezing is performed by introducing said atomized formulation into a fluid or medium having a temperature below the freezing point of said liquid formulation.
9. The pharmaceutical composition of claim 8, wherein said fluid or medium has a boiling point or sublimation point lower than that of said atomized formulation.
10. The pharmaceutical composition of claim 8, wherein said fluid is a gas.
11. The pharmaceutical composition of claim 8, wherein said fluid is a liquid.
12. The pharmaceutical composition of claim 1, wherein said dried particles are further dried by lyophilization.
13. The pharmaceutical composition of claim 1, wherein said particles are dried in the presence of a flowing stream of gas.
14. The pharmaceutical composition of claim 1, wherein said atomizing, freezing and drying are carried out in a continuous process.
15. The pharmaceutical composition of claim 1, wherein said atomizing, freezing and drying are carried out in a single vessel.
16. The pharmaceutical composition of claim 1, wherein said therapeutic agent is a protein, a nucleic acid or a virus particle.
17. The pharmaceutical composition of claim 1, wherein said therapeutic agent is an immunogenic agent.
18. The pharmaceutical composition of claim 17, wherein said immunogenic agent is an influenza vaccine.

19. The pharmaceutical composition of claim 18, wherein said influenza vaccine comprises inactivated influenza virus particles or a nucleic acid encoding an influenza haemagglutinin protein, which is operatively linked to a CMV promoter.
20. The pharmaceutical composition of claim 1, wherein said therapeutic agent is insulin.
21. The pharmaceutical composition of claim 1, wherein said liquid formulation comprises a mucoadhesive.
22. The pharmaceutical composition of claim 21, wherein said mucoadhesive is chitosan, dermatan sulfate, chondroitin, or pectin.
23. The pharmaceutical composition of claim 1, wherein said liquid formulation of said therapeutic agent consists essentially of said therapeutic agent and water.
24. A pharmaceutical composition prepared by drying at about atmospheric pressure, in the presence of vibration, internals, mechanical stirring or a combination thereof, solid particles which have been formed by freezing an atomized formulation of a liquid formulation of a therapeutic or prophylactic agent.
25. A method of preparing a pharmaceutical composition, comprising atomizing a liquid formulation of a therapeutic agent to produce an atomized formulation, freezing said atomized formulation to form solid particles, and drying said solid particles at about atmospheric pressure to produce dried particles, wherein said drying is performed in the presence of vibration, internals, mechanical stirring, or a combination thereof.
26. The method of claim 25, wherein said frozen, solid particles are in a fluidized state as they are being dried.
27. The method of claim 25, wherein said dried particles have a volume mean diameter of between about 35 μ m and about 300 μ m.

28. The method of claim 25, wherein said dried particles have a volume mean diameter of between about 50 μ m and about 100 μ m.
29. The method of claim 27, wherein at least about 50% of said dried particles have a volume diameter within about 80% of the mean.
30. The method of claim 25, wherein said dried particles have an average mean aerodynamic diameter of between about 8 μ m and about 140 μ m
31. The method of claim 25, wherein said dried particles have an average mean aerodynamic diameter of between about 20 μ m and about 70 μ m.
32. The method of claim 25, wherein said freezing is performed by introducing said atomized formulation into a fluid or medium having a temperature below the freezing point of said liquid formulation.
33. The method of claim 32, wherein said fluid or medium has a boiling point or sublimation point lower than that of said atomized formulation.
34. The method of claim 32, wherein said fluid is a gas.
35. The method of claim 32, wherein said fluid is a liquid.
36. The method of claim 25, further comprising drying said dried particles by lyophilization.
37. The method of claim 25, wherein said particles are dried in the presence of a flowing stream of gas.
38. The method of claim 25, wherein said atomizing, freezing and drying are carried out in a continuous process.

39. The method of claim 25, wherein said atomizing, freezing and drying are carried out in a single vessel.
40. The method of claim 25, wherein said therapeutic agent is a protein, a nucleic acid or a virus particle.
41. The method of claim 25, wherein said therapeutic agent is an immunogenic agent.
42. The method of claim 41, wherein said immunogenic agent is an influenza vaccine.
43. The method of claim 42, wherein said influenza vaccine comprises inactivated influenza virus particles or a nucleic acid encoding an influenza haemagglutinin protein, which is operatively linked to a CMV promoter.
44. The method of claim 25, wherein said therapeutic agent is insulin.
45. The method of claim 26, wherein said liquid formulation comprises a mucoadhesive.
46. The method of claim 45, wherein said mucoadhesive is chitosan, dermatan sulfate, chondroitin, or pectin.
47. The method of claim 25, wherein said liquid formulation of said therapeutic agent consists essentially of said therapeutic agent and water.
48. A method of preparing a pharmaceutical composition, comprising drying at about atmospheric pressure, in the presence of vibration, internals, mechanical stirring or a combination thereof, solid particles which have been formed by freezing an atomized formulation of a liquid formulation of a therapeutic agent.
49. A method of treatment, comprising administering to a patient in need thereof an effective amount of a pharmaceutical composition of claim 1.

50. The method of claim 49, wherein said composition is administered by a respiratory, intranasal, intrarectal, intravaginal, sublingual, or parenteral route.

51. The method of claim 49, wherein said composition is administered intranasally.

52. The method of claim 49, wherein said composition is administered to a mucosal membrane.

53. A method of treatment, comprising administering to a patient in need thereof an effective amount of a pharmaceutical composition of claim 8.

54. A method of treatment, comprising administering to a patient in need thereof an effective amount of a pharmaceutical composition of claim 16.

55. A method of treatment, comprising administering to a patient in need thereof an effective amount of a pharmaceutical composition of claim 17.

56. A method of treatment, comprising administering to a patient in need thereof an effective amount of a pharmaceutical composition of claim 18.

57. A method of treatment, comprising administering to a patient in need thereof an effective amount of a pharmaceutical composition of claim 19.

58. A method of treatment, comprising administering to a patient in need thereof an effective amount of a pharmaceutical composition of claim 20.

59. A method of treatment, comprising administering to a patient in need thereof an effective amount of a pharmaceutical composition of claim 21.

60. A method of reducing the amount of a therapeutic or prophylactic agent that is required to produce an efficacious result following intranasal administration to a patient in need thereof, comprising administering to said patient, intranasally, an effective amount a pharmaceutical composition of claim 1.

61. A method of eliciting an immune response in a patient, comprising administering to said patient an effective amount of an immunogenic composition of claim 17.

62. The method of claim 61, wherein said composition is administered intranasally.

63. The method of claim 62, wherein said immunogenic composition is an influenza vaccine.

64. The method of claim 63, wherein said influenza vaccine comprises a nucleic acid encoding an influenza haemagglutinin protein, which is operatively linked to a CMV promoter.

65. The method of claim 63, wherein said influenza vaccine comprises inactivated influenza virus particles or a subunit of a flu virus.

66. The method of claim 49 wherein said immunogenic composition is administered as a part of a prime-boost regimen.

67. The method of claim 66 wherein a priming immunization is administered as said immunogenic composition, and a boosting immunization is a viral preparation.

68. The method of claim 66 wherein a priming immunization is administered intranasally, and a boosting immunization is delivered intramuscularly.

69. A vaccine composition made by a method comprising
atomizing a liquid formulation of a therapeutic or prophylactic agent to produce an
atomized formulation,
freezing said atomized formulation to form solid particles, and
drying said solid particles to produce dried particles.

70. A method of reducing the amount of a therapeutic or prophylactic agent that is required to produce an efficacious result following parenteral administration to a patient in need thereof, comprising administering to said patient, parenterally, an effective amount a reconstituted vaccine composition of claim 69.

71. The vaccine composition of claim 69, wherein said vaccine is a recombinant staphylococcal enterotoxin B vaccine.

72. A method of preparing a vaccine composition, comprising
atomizing a liquid formulation of a prophylactic or therapeutic agent to produce an
atomized formulation,
freezing said atomized formulation to form solid particles, and
drying said solid particles to produce dried particles.

73. The method of claim 72, wherein said vaccine is a recombinant staphylococcal enterotoxin B vaccine.

74. A method of treatment, comprising administering to a patient in need thereof an effective amount of a vaccine composition of claim 69.

75. The method of claim 74, wherein said vaccine composition is a recombinant staphylococcal enterotoxin B vaccine.